IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: TERLECKY1A

In re Application of:

(Commissioner for Patent Examination Policy

Patent No.: 7,601,366

Patent Date: October 13, 2009

For: RESTORATION OF

PEROXISOMAL CATALASE IN

HUMAN CELLS

ATTY.'S DOCKET: TERLECKY1A

(Commissioner for Patent Date Deputy

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REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window
Randolph Building, Mail Stop Petitions
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 37 CFR 1.705(d), reconsideration of the patent term adjustment indicated on the face of the above-identified patent is hereby requested.

In accordance with 37 CFR 1.705(b)(1), submitted herewith is the fee of \$200 as set forth in 37 CFR 1.18(e). If there is any underpayment or any other fee necessary for consideration of this request, please charge same to the deposit account no. 02-4035 of the undersigned.

Grounds for Correction Notwithstanding the Wyeth Case

The following statement of the facts involved is in compliance with 37 CFR 1.705(b)(2). The correct patent term adjustment is 529 days. The period of delay under 37 CFR 1.702(a) is 396 days, as properly calculated by the PTO. However, the PTO failed to properly calculate the non-overlapping period of delay under 37 CFR 1.702(b). The latter requires that "the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the ... national stage commenced under 35 U.S.C. 371(b)" It is apparent that the PTO erroneously used the 371(c) date, as otherwise the PTO would have determined that the 1.702(b) date was longer than the 1.702(a) date.

The date of commencement of the national stage under 35 U.S.C. 371(b) in this case was April 30, 2005. Thus, the period of time from April 30, 2008 (three years after the 371(b) date) to issuance of the patent on October 13, 2009, was 531 days. Subtracting the 2 days of applicant delay calculated by the PTO, the Patent Term Adjustment for the present application should be no less than 529 days, as required by 1.702(b), as opposed to the smaller 394 day PTA calculated under 1.702(a). Accordingly, the PTO erred in calculating the PTA and the PTA should be corrected to 529 days.

Grounds for Correction in Light of the Wyeth Case

The following statement of the facts involved is in compliance with 37 CFR 1.705(b)(2). The correct patent term adjustment is 914 days. The period of delay under 37 CFR 1.702(a) is 396 days, as properly calculated by the PTO. However, the PTO failed to take into account the non-overlapping period of delay under 37 CFR 1.702(b). The period of time from April 30, 2008 (three years after the 371(b) date - see discussion above) to issuance of the patent on October 13, 2009, was 531 days.

under 1.702 are added together "to the extent that such periods are not overlapping." In Wyeth v. Dudas, 2008 U.S. Dist. LEXIS 76063, 88 USPQ2d 1538 (D.D.C. Sept. 30, 2008), the U.S. District Court for the District of Columbia held that only periods of actual calendar days overlap between the time periods of delay calculated under 1.702(a) and 1.702(b) are to be considered as overlap within the meaning of 1.703(f). Thus, in this case, the only days of "overlap" are the 11 days of delay under 1.702(a) that occurred after April 30, 2008, which was the commencement of the 1.702(b) delay. The 383 days of 1.702(a) delay that occurred prior to the commencement of the 1.702(b) delay must be added to the 531 days of delay under 37 CFR 1.702(b) to determine the total PTO delay, as per the interpretation required by the Wyeth court.

Thus, the period of patent term adjustment by the interpretation approved by the court in Wyeth v. Dudas, supra, is 396 + 531 - 11 = 916 days, minus any period attributed to applicant's delay (37 CFR 1.704). The PTO calculated applicant's delay as 2 days. Thus, using the PTO's figures and the court's interpretation, the correct period for patent term adjustment should have been 914 days, i.e., 916-2=914days. No terminal disclaimer has been filed in this case.

Conclusion

If the Wyeth case is affirmed by the Court of Appeals for the Federal Circuit, the total PTA should be 914 days for this case. However, if the Wyeth District Court decision is reversed by the Federal Circuit, or pending such a decision, the PTA should be amended to 529 days, as the PTO erroneously calculated the PTA even using the rules that it was purportedly using at the time of issuance of this patent.

These issues could not have been raised on or before the date of payment of the issue fee as the period of adjustment under 1.702(b) did not become determined until the patent issued. Indeed, the PTO does not consider the effect of the 1.702(b) period until it mails the issue notification.

Accordingly, this request for reconsideration of the patent term adjustment is timely under 37 CFR 1.705(d).

Granting of this request and modifying the patent term adjustment afforded this case to a total of 914 days, or at least to a total of 529 days, are therefore earnestly solicited.

Respectfully submitted,

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